**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION | MDL No. 2419<br>Dkt. No. 1:13-md-2419 (RWZ) |
| THIS DOCUMENT RELATES TO:<br><br>Dkt. No. 1661 | |

**DECLARATION OF THOMAS M. SOBOL IN SUPPORT OF THE PLAINTIFFS' STEERING COMMITTEE'S OPPOSITION TO LIBERTY INDUSTRIES, INC.'S MOTION TO STRIKE THE AMENDED DECLARATION OF PHILIP J. AUSTIN, PH.D.**

I, Thomas M. Sobol, declare as follows:

1. I am a partner in the Boston office of the law firm Hagens Berman Sobol Shapiro LLP, and Lead Counsel in the *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 2419, Civil Action No. 1:13-md-2419-FDS, in the United States District Court for the District of Massachusetts.

2. I submit this declaration in support of the Plaintiffs' Steering Committee's opposition to Liberty Industries, Inc.'s motion to strike the amended declaration of Dr. Austin.

3. Attached hereto are true and accurate copies of the following documents:

   a. Exhibit 1: Excerpt of USP-NF General Chapter <797> Pharmaceutical Compounding-Sterile Preparations, USP 35/NF 30 (2012);

   b. Exhibit 2: Excerpt of deposition transcript of Jeffrey Erickson (November 18, 2014); and

   c. Exhibit 3: Excerpt of deposition transcript of Robert Kaiser (November 18, 2014).

Declared under the penalties and pains of perjury.

January 26, 2015

**/s/ Thomas M. Sobol**
Thomas M. Sobol

# EXHIBIT 1

2012

# USP 35
# NF 30

## *USP–NF* General Chapter <797>

## Pharmaceutical Compounding—
## Sterile Preparations

U.S. PHARMACOPEIA
*The Standard of Quality*℠

# ⟨797⟩ PHARMACEUTICAL COMPOUNDING–STERILE PREPARATIONS

## INTRODUCTION

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ and *Good Compounding Practices* ⟨1075⟩) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ include, but are not limited to, ISO-classified air environments (see *Table 1*); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see *Table 1*) sources.

**Table 1. ISO Classification of Particulate Matter in Room Air**
(limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])*

| Class Name | | Particle Count | |
|---|---|---|---|
| ISO Class | U.S. FS 209E | ISO, $m^3$ | FS 209E, $ft^3$ |
| 3 | Class 1 | 35.2 | 1 |
| 4 | Class 10 | 352 | 10 |
| 5 | Class 100 | 3,520 | 100 |
| 6 | Class 1,000 | 35,200 | 1,000 |
| 7 | Class 10,000 | 352,000 | 10,000 |
| 8 | Class 100,000 | 3,520,000 | 100,000 |

*Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per $m^3$ or larger (ISO Class 5) is equivalent to 100 particles per $ft^3$ (Class 100) (1 $m^3$ = 35.2 $ft^3$).

The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [NOTE—The FDA states that "Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

## ORGANIZATION OF THIS CHAPTER

The sections in this chapter are organized to facilitate the practitioner's understanding of the fundamental accuracy and quality practices for preparing CSPs. They provide a

# EXHIBIT 2

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

MDL No. 2419

Master Dkt.

1:13-md-02419-RWZ

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THIS DOCUMENT RELATES TO:

All Actions

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VIDEOTAPED DEPOSITION OF JEFFREY C. ERICKSON

Tuesday, November 18, 2014

9:09 a.m.

Royal Sonesta Boston Hotel

Room Skyline E, West Tower

40 Edwin H. Land Boulevard

Cambridge, Massachusetts

Michelle Keegan, Court Reporter

A. I have read articles related to the amount of monitoring personnel, better for clean room applications.

Q. I'm sorry. I missed that.

A. By monitoring -- reading articles related to monitoring of personnel, how they come into the room and how they react within their protocols.

Q. Are you familiar with the USP 797?

A. Yes.

MR. REHNQUIST: Objection.

Q. I'm sorry?

A. Yes, I'm aware.

Q. Is that something that you refer to in the course of your employment?

A. Yes.

Q. And how do you use it?

A. When a customer calls up with a request for a clean room and they give us the protocols that they're looking for related to USP, that's how we design the room, and using the guidelines.

Q. So you would take the USP. You'd be told these are the parts of USP 797, for example, that we need to have a room designed to meet, and then you'd apply that to your design and construction of the clean room that

Q. So the '08 project goes from a 7 to a 6 to a 5?
A. Yes.
Q. And the '06 project goes from a 7 to a 7 to a -- it's hard to read this. Is that a 6 to a 6?
A. I believe it's a 6.
Q. A 6 to 6?
A. A 7 to a 6. On this drawing, the personnel room appears to be a 7, the preparation area is a 7, and then the main clean room is the 6.
Q. Okay. And then there's a freight anteroom. What is that?
A. I believe that is an 8.
Q. So the traffic flow here would be from the hallway into the personnel room and then directly into the clean room or into the preparation room, but not from -- you don't go from preparation, it looks like, directly into the clean room?
A. Yes, you can. There is --
Q. Am I missing a door?
A. There is a door right in the middle of that wall dividing it into two rooms. It looks like two thin rectangles.
Q. Got it. Is that standard design to be able to go from the personnel into the clean room itself? Is

second sentence.

A. Yes.

Q. So earlier you talked about how there are some projects where Liberty might be subcontracted out to provide a component of a clean room. Correct?

A. Yes.

Q. This 2006 clean room, the -- what we'll call the main NECC clean room, that was not one of those projects. Right?

MR. HERMES: Objection.

A. No, it was not.

Q. Because this is a project where you, Liberty, was providing the full design, engineering, and project management to build that clean room. Right?

MR. HERMES: Objection.

A. For the architectural portion of this project.

Q. Was this the largest clean room you'd ever built as of this date in 2006?

A. In 2006, I would say yes.

Q. And at that time when you were providing the design services -- the full design services for this project, did you have any understanding as to the purpose for which the clean room was going to be put to use?

MR. HERMES: Objection.

A. Other than compounding, as a general statement.

Q. And what did you know about compounding in 2006?

A. Nothing.

Q. And so you didn't know whether or not this was going to be a sterile compounding facility or a nonsterile compounding facility. Right?

A. I'm unaware of being told one or the other.

Q. In connection with the design services you provided to NECC for this 2006 clean room, did you ever review the FDA's good manufacturing practices for sterile drug products in aseptic processing?

A. I know of the document. I can't recall if I reviewed it prior to.

Q. Have you reviewed it since?

A. Since the 2006 date, I'm pretty sure I have. I'd say yes.

Q. When is the first time you recall reviewing that document?

A. I don't -- I can't recall.

Q. Recently?

A. I have not looked recently.

Q. Do you have any reason to believe that you have

# EXHIBIT 3

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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THIS DOCUMENT RELATES TO:

All Actions

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VIDEOTAPED DEPOSITION OF ROBERT KAISER

Tuesday, November 18, 2014

2:57 p.m.

Royal Sonesta Boston Hotel

Room Skyline E, West Tower

40 Edwin H. Land Boulevard

Cambridge, Massachusetts

Michelle Keegan, Court Reporter

new clean room for additional capacity or whether they were going to consolidate and make one great big one.

Q. Okay. Thank you.

(Exhibit Number 20 marked for identification)

Q. I've marked Exhibit 20 for you.

A. Thank you.

Q. Here is one for your counsel.

MR. HERMES: Thank you.

Q. This is also a document which I took off of your website, and it refers to "USP-797 Compliant Clean Rooms."

Is this content that you had a part in drafting?

A. Yes.

Q. Do you recall if you drafted the entire thing or some of it?

A. I would say probably a good part of it, which in large part may have been taken directly from our catalog.

Q. Okay. The first line states that "On January 1, 2004, USP 797 regulations went into effect. These regulations are FDA enforceable."

What does "FDA enforceable" mean?

were engaged in the compounding of sterile preparations?

A. We knew they did drug compounding, not necessarily sterile.

Q. When did you learn that NECC did sterile?

MR. HERMES: Objection.

Q. I'm sorry. Do you know today that they did sterile?

A. I do now, yes.

Q. Sorry. When did you learn that they did sterile?

MR. HERMES: Objection. It's not sterile. They've proven that.

MR. LIPTON: Intended.

MR. JARNAGIN: That's a good point, Peter.

A. To be honest with you, I don't remember.

Q. Do you agree that Liberty markets its clean rooms as being USP 797 compliant?

A. If it is for a pharmacy hospital environment, yes.

Now, one thing I think is important to say is, we really only know what the customer tells us. They will call and say, "I want a clean room."

We will say, "What are you going to do?"

They say, "We're going to do XYZ." They say

they're a pharmacy.

"Yes, we do."

If they say no, they're going to do electronics, then this doesn't count. But in many cases we really don't know exactly what they really do.

Q. On the third page, in the bottom right corner it says 3 of 8, I think.

A. Yup.

Q. Here it looks like there's a -- two different types of clean rooms that Liberty sells. Can you tell me which clean rooms here went into the NECC facility?

A. By the words on this page, it's a permanent Liberty clean room.

Q. Okay. All three of them?

A. No. I would say the one on the bottom is really showing a pass-through, not so much a clean room, but it looks like it's in a permanent clean room wall.

MR. HERMES: I think the witness may have misunderstood the question.

MR. JARNAGIN: That's fine.

Q. Were all three of the clean rooms built by Liberty at NECC's facility the type called "permanent Liberty compounding clean rooms"?

A. Correct.